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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,757	11/20/2001	Linda M. Western	BEH-7270 Cont.	9649

34500 7590 10/01/2003

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
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1637

9

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,757

Applicant(s)

WESTERN ET AL.

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. This action is in response to Paper No. 7, filed on February 21, 2002. Currently, claims 35-41 are pending and are rejected. This action is made NON-FINAL.

Specification

2. On page 1, Applicants should amend the specification to provide the appropriate continuation data, i.e., Applicants should amend the specification to reflect that US Application No. 09/608,721 is now US Patent No. 6,368,803.

Information Disclosure Statement

3. The information disclosure statement of Paper No. 7 complies with CFR 1.97, 1.98, and M.P.E.P. 609, and has been considered (see enclosed signed PTO-1449). However, it is noted that the non-patent literature (references C1-C7) did not appear in the application and therefore, it has not been considered. It is noted that the instant application has changed location from the previous examiner to the examiner listed below. Applicants should resubmit references C1-C7.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is indefinite because it is not clear as to how an oligonucleotide can comprise

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“about” 1 nucleotide. That is, this claim language encompasses less than one nucleotide, and it is not clear as to how an oligonucleotide can have less than one nucleotide.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 35-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gelfand et al (US Patent No. 5,210,015, cited in the IDS).

The claims are drawn to a composition comprising two oligonucleotides, the “first oligonucleotide” capable of reversibly hybridizing to a polynucleotide analyte under isothermal conditions to at least a portion” of a target polynucleotide, and a “second oligonucleotide capable of hybridizing to the polynucleotide analyte, wherein the “first oligonucleotide” comprises a 3’ portion that is substantially complementary to said polynucleotide analyte, and a 5’ portion which does not hybridize to the polynucleotide analyte, wherein the “second oligonucleotide” hybridizes to said polynucleotide analyte at a location in the 3’ direction from the “first oligonucleotide”.

Gelfand teaches a method for detection of a target nucleic acid utilizing a 5'-nuclease and two oligonucleotides, a “labeled oligonucleotide” and a “first oligonucleotide,” that contain sequences that are complementary to different regions of the same target (see, for example, col 2,

“under hybridization conditions, conditions which enable the binding of the primers and probes to the single nucleic acid strands” (col 8, lines 4-7). In reference to any oligonucleotide and target sequence, the term “hybridization conditions” inherently indicates reversible hybridization under isothermal conditions. It is an inherent property of any oligonucleotide with an unblocked 5' end that it would reversibly hybridize under isothermal conditions and, further, that it could be degraded at its 5' end by a 5' nuclease. Gelfand teaches that his “labeled oligonucleotide,” like the “first oligonucleotide” of the instant claims, is cleaved by a 5'-nuclease; this cleavage causes the release of fragments that may comprise mononucleotides or small oligonucleotides (col 2, lines 23-47; claim 1; col 7, lines 11-15). Thus, Gelfand’s “labeled oligonucleotide” may be “degraded” to provide a “first fragment that is substantially non-hybridizable” to a target and a “second fragment that is 3' of said first fragment “ and “substantially hybridizable to said polynucleotide,” as recited in the instant claims. Gelfand’s “first oligonucleotide”, like the “second oligonucleotide” of the instant claims, anneals to the target “such that the 3' end of the first oligonucleotide is adjacent to the 5' end of the labeled oligonucleotide” (col 2, lines 35-39); Gelfand discloses that “adjacent” oligonucleotides may abut one another, or be separated by “1 to about 20 nucleotides” (col 5, lines 61-67). Gelfand also teaches that two oligonucleotides can be labeled, either on their 5' or 3' ends (col. 10, ln. 51-68).

8. Claims 35-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Carrino et al. (USPN 5,573,907, cited in the IDS).

Carrino teaches a composition comprising two oligonucleotides, the “first oligonucleotide” capable of reversibly hybridizing to a polynucleotide analyte under isothermal conditions to at least a portion” of a target polynucleotide, and a “second oligonucleotide capable of hybridizing to the polynucleotide analyte, wherein the “first oligonucleotide” comprises a 3' portion that is substantially complementary to said polynucleotide analyte, and a 5' portion

which does not hybridize to the polynucleotide analyte, wherein the “second oligonucleotide” hybridizes to said polynucleotide analyte at a location in the 3’ direction from the “first oligonucleotide” (see col. 2-4, 7-8, 12-14, 18-19 and 41-42, for example). Carrino also teaches the either one or both of the probes can be labeled either in the 5’ or 3’ end (col. 18-19); and 5’ portion of the first oligonucleotide can comprise about 1 to 40 nucleotides (col. 7, 9-10 and 41-42) (teaching that the 5’ portion of the first oligonucleotide can be any size).

9. Claims 35-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Urdea et al. (USPN 5,635,352).

Urdea teaches a composition comprising two oligonucleotides, the “first oligonucleotide” capable of reversibly hybridizing to a polynucleotide analyte under isothermal conditions to at least a portion” of a target polynucleotide, and a “second oligonucleotide capable of hybridizing to the polynucleotide analyte, wherein the “first oligonucleotide” comprises a 3’ portion that is substantially complementary to said polynucleotide analyte, and a 5’ portion which does not hybridize to the polynucleotide analyte, wherein the “second oligonucleotide” hybridizes to said polynucleotide analyte at a location in the 3’ direction from the “first oligonucleotide” (see Figs. 1-4, 7, 12-13, and cols. 2-3, 5-6, 10-13, for example). Urdea also teaches the either one or both of the probes can be labeled either in the 5’ or 3’ end (col. 16 and Figs. 1-4, 7, 12-13); and 5’ portion of the first oligonucleotide can comprise about 1 to 40 nucleotides (Figs. 1-4, 7, 12-13, col. 6-12 and Examples 1-5) (teaching that the 5’ portion of the first oligonucleotide can be any size).

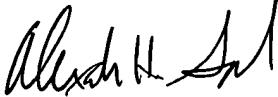
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Correspondence

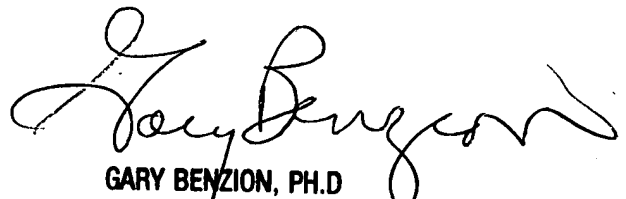
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alexander H. Spiegler
September 29, 2003



GARY BENZION, PH.D
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